SSR Institute of International Journal of Life Sciences
ISSN (O): 2581-8740 | ISSN (P): 2581-8732
Anusha *et al*., 2026
doi: 10.21276/SSR-IIJLS.2026.12.4.50

Original Article

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Sociodemographic Profile and Physical Comorbidity Burden of Patients on DOTS-Plus Therapy and their Relationship with Anxiety and Depression

Anusha VG[1]*, Vijayalaxmi Purad[2], Anand M[3], Kasturi Pandiyan[4]

[1]Assistant Professor, Dept. of Psychiatry, BGS GIMS Medical College and Research Hospital Bengaluru, India

[2]Senior Resident, Dept. of psychiatry, Belagavi Institute of Medical Sciences, Belagavi, India

[3]District Leprosy Officer, Bengaluru Urban, Bengaluru, India

[4]Professor & HOD, Dept of Psychiatry, MVJ Medical College and Research Hospital, Bengaluru, India

***Address for Correspondence:** Dr Anusha VG, Assistant Professor, Dept. of Psychiatry, BGS GIMS Medical College and Research Hospital, Bengaluru, India
E-mail: aksharagaddi@gmail.com

Received: 21 Mar 2026/ Revised: 13 May 2026/ Accepted: 20 Jun 2026

ABSTRACT

Background: Tuberculosis is more common among socially and economically disadvantaged populations and is often associated with chronic physical illnesses that may increase the risk of anxiety and depression. However, limited data are available on the sociodemographic and clinical profile of patients receiving DOTS-Plus therapy in rural India. The present study aimed to assess these characteristics, including physical comorbidities, and their distribution across different levels of anxiety and depression.

Methods: One hundred patients aged 18–70 years with pulmonary or extrapulmonary tuberculosis, 4–8 weeks after starting DOTS-Plus therapy, were studied over 18 months at a rural medical college hospital using a cross-sectional design. Sociodemographic and clinical data were collected using a semi-structured proforma, while psychiatric diagnoses and severity were assessed using MINI-Plus, ICD-10, HAM-A, and HAM-D. Chi-square and Fisher's exact tests were used, with $p<0.05$ considered significant.

Results: Patients were mainly aged 31–50 years (56%), with 51% females, 84% from lower socioeconomic backgrounds, and 82% married. Common comorbidities were hypertension (36%), hyperthyroidism (24%), COPD (23%), diabetes and hypothyroidism (19% each), and asthma (16%). Anxiety (16) and depression (22) were more common among vulnerable groups, but no sociodemographic factor significantly affected severity ($p>0.05$).

Conclusion: Patients receiving DOTS-Plus therapy in this rural setting were socioeconomically disadvantaged, poorly educated and burdened with chronic comorbidities. Anxiety and depression were more common in these vulnerable groups, although statistical significance was limited by small numbers. Rural TB services should integrate physical, mental health and social care.

Key-words: Tuberculosis; DOTS-Plus; Sociodemographic factors; Comorbidity; Anxiety; Depression

INTRODUCTION

Tuberculosis (TB) has long been recognized as a disease of poverty. India carries the world's largest TB burden, with an estimated incidence of 188 per 100,000 population in 2020 and 19,33,381 incident patients notified in 2021 [1].

How to cite this article
Anusha VG, Purad V, Anand M, Pandiyan K. Sociodemographic Profile and Physical Comorbidity Burden of Patients on DOTS-Plus Therapy and their Relationship with Anxiety and Depression. SSR Inst Int J Life Sci., 2026; 12(4): 10506-10513.

Access this article online
https://iijls.com/

Since the adoption of the Directly Observed Treatment, Short-course strategy under the Revised National Tuberculosis Control Programme in 1997, and its subsequent evolution into the National Tuberculosis Elimination Programme, case notification has risen substantially, but the disease continues to concentrate among the poor, the malnourished, the poorly educated and those living in crowded conditions [2,3]. Understanding the profile of patients who actually present for treatment is therefore not merely descriptive: it defines the population in which any programmatic intervention must work. Two features of that profile have attracted increasing attention.

doi: 10.21276/SSR-IIJLS.2026.12.4.50

The first is physical multimorbidity. Diabetes mellitus roughly triples the risk of active tuberculosis and worsens treatment outcomes, and the convergence of the diabetes and TB epidemics in South Asia has been described as a looming co-epidemic [4]. Chronic obstructive pulmonary disease and asthma are both a consequence and a risk factor for tuberculosis, with post-tubercular structural lung damage a well-recognized sequel [5]. Hypertension, thyroid disorders and other chronic conditions add further complexity to a regimen that is already long, multidrug and poorly tolerated. Physical comorbidity in TB is associated with more adverse drug reactions, greater pill burden and reduced adherence [6].

The second is psychiatric comorbidity. Tuberculosis and common mental disorders share risk factors including poverty, substance misuse, malnutrition, homelessness and social exclusion, an overlap sometimes described as a syndemic [7]. A systematic review and meta-analysis estimated the pooled prevalence of depression among TB patients at approximately 45% [8], and Indian studies have reported depression in about 24% to 41% of patients on treatment [9-11]. Anxiety and depression in TB are in turn associated with reduced treatment compliance, longer treatment courses, poorer disease control and increased mortality [12,13]. Sociodemographic factors reported to influence this burden include age, sex, marital status, education, income and social support, though findings have been inconsistent: some authors report significant associations with age, unmarried status and low education [14], while others find that neither sex, marital status nor education modifies the risk [10].

Where these two strands meet is in the patient who is simultaneously poor, poorly educated, physically multimorbid and psychologically distressed. Such patients are common in rural India yet are rarely characterized in detail, because most published Indian work on psychiatric comorbidity in tuberculosis has been conducted in urban tertiary centres or in specific populations such as armed forces personnel or multidrug-resistant cohorts [11,15]. Rural DOTS-Plus attendees may differ substantially in literacy, occupation, socioeconomic position, health-seeking behaviour and exposure to stigma.

The present study was therefore undertaken in a rural medical college hospital to describe in detail the sociodemographic characteristics, clinical features and physical comorbidity burden of patients receiving DOTS-Plus therapy, and to examine how patients affected by anxiety and depression are distributed across these characteristics. The pattern and severity of psychiatric diagnoses in this cohort, including the comparison between pulmonary and extrapulmonary disease, are reported separately; the present report concerns the patient profile and its relationship to psychological morbidity.

MATERIALS AND METHODS

Study Design and Setting- This cross-sectional observational study was carried out over 18 months (February 2021 to July 2022) in the Department of Respiratory Medicine of a medical college and research hospital located at Hoskote, a rural area of Bengaluru Rural district, in collaboration with the Department of Psychiatry. Institutional Ethics Committee approval was obtained before the study commenced, and written informed consent was taken from every participant.

Study Population and Eligibility Criteria- The study population comprised patients diagnosed with tuberculosis by the chest physician and attending the Department of Respiratory Medicine. Patients of either sex aged 18–70 years, with either pulmonary or extrapulmonary tuberculosis, who were 4–8 weeks after initiation of the DOTS-Plus regimen were eligible. This interval was chosen deliberately to allow the acute distress of a new diagnosis to settle while capturing the early treatment phase during which adverse drug effects and adherence problems typically emerge.

Patients already diagnosed with a psychiatric illness and receiving treatment for it were excluded so that pre-existing disorders would not be misattributed to tuberculosis. Patients with HIV co-infection were also excluded to avoid confounding by HIV-related neuropsychiatric morbidity.

Sample Size and Sampling- The sample size was calculated using the standard formula for estimating a single proportion, with a 95% confidence level (Z = 1.96) and an absolute precision of 0.08, giving a minimum requirement of 94 subjects [16]; this was rounded to 100. Participants were selected by simple random sampling from the register of eligible patients.

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Data Collection- A semi-structured proforma designed for the study was used to record sociodemographic variables, including age, sex, education, socioeconomic status, and marital status, along with clinical variables such as type of tuberculosis, duration of illness in months, and comorbid medical conditions.

Comorbidity was recorded as a multiple-response variable, since patients could have more than one chronic condition. Diagnoses of diabetes mellitus, hypertension, chronic obstructive pulmonary disease, asthma, hypothyroidism, and hyperthyroidism were accepted on the basis of documented physician diagnosis and ongoing treatment, supplemented by clinical examination.

Psychiatric Assessment- Psychiatric assessment was carried out by a single trained clinician. All participants were interviewed with the Mini International Neuropsychiatric Interview-Plus (MINI-Plus), a short structured diagnostic interview for DSM-IV and ICD-10 disorders requiring approximately 15 minutes [17], and diagnoses were confirmed against ICD-10 clinical descriptions and diagnostic guidelines [18].

Severity was then graded with two clinician-rated instruments: the Hamilton Anxiety Rating Scale (HAM-A), comprising 14 items each scored 0–4 for a total of 0–56 [19], and the Hamilton Depression Rating Scale (HAM-D), in which a score of 0–7 on the 17-item version is regarded as normal and 20 or above indicates at least moderate depression [20]. Use of a single rater minimized inter-observer variation.

Statistical Analysis- Data were analysed using SPSS 22.0. Quantitative and qualitative variables were summarized as mean ± SD and frequencies/proportions, respectively. Associations were assessed using Chi-square/Fisher's exact tests and group means using the unpaired t-test. $p<0.05$ was considered significant and $p<0.001$ highly significant.

RESULTS

One hundred patients receiving DOTS-Plus therapy for pulmonary or extrapulmonary tuberculosis were studied. Patients were concentrated in the economically productive years: 29% were aged 41–50 years and 27% were aged 31–40 years, so that 56% of the cohort fell within the 31–50 year band. Only 3% were younger than 20 years and 10% were older than 60 years. Males and females were almost equally represented, with a marginal female preponderance (51% versus 49%) (Table 1).

Table 1: Age and sex distribution of the study participants (n = 100)

Variable	Category	n	%
Age (years)	<20	3	3
	21–30	14	14
	31–40	27	27
	41–50	29	29
	51–60	17	17
	>60	10	10
Sex	Male	49	49
	Female	51	51
	Total	100	100

Educational attainment was modest: although 40% had reached secondary or higher secondary level and 17% were graduates, a substantial 43% were either illiterate (8%) or had studied only up to primary level (35%). The socioeconomic distribution was strikingly skewed, with 84% of patients belonging to the lower stratum against 11% upper and 5% middle. Most patients were married (82%) (Table 2).

doi: 10.21276/SSR-IIJLS.2026.12.4.50

Table 2: Education, socioeconomic status and marital status (n = 100)

Variable	Category	n	%
Education	Illiterate	8	8
	Primary	35	35
	Secondary/ Higher secondary	40	40
	Graduate	17	17
Socioeconomic status	Lower	84	84
	Middle	5	5
	Upper	11	11
Marital status	Married	82	82
	Unmarried	18	18

Physical comorbidity was widespread. Hypertension was the single commonest condition, affecting more than one-third of the cohort (36%). Thyroid dysfunction taken together affected 43% of patients (hyperthyroidism 24%, hypothyroidism 19%). Chronic airway disease was also prominent, with chronic obstructive pulmonary disease in 23% and asthma in 16%, giving a combined chronic respiratory comorbidity of 39%. Diabetes mellitus was present in 19% (Table 3).

Table 3: Physical comorbidity among the study participants (n = 100)

Comorbid condition*	n	%
Hypertension	36	36
Hyperthyroidism	24	24
Chronic obstructive pulmonary disease	23	23
Diabetes mellitus	19	19
Hypothyroidism	19	19
Asthma	16	16

**Multiple-response variable; a patient could report more than one condition, so percentages do not total 100.*

The overwhelming majority of patients (94%) had been ill for less than 12 months, consistent with recruitment at 4–8 weeks after initiation of therapy; only 6% reported an illness duration exceeding 12 months, representing patients with prolonged, relapsed or previously interrupted disease (Table 4).

Table 4: Duration of tubercular illness (n = 100)

Duration of illness (months)	n	%
<12	94	94
>12	6	6
Total	100	100

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Psychiatric morbidity was identified in 53 patients (53%). Of these, 22 patients (22% of the whole cohort) had a depressive disorder and 16 (16%) an anxiety disorder; the remainder comprised substance use, somatoform and psychotic disorders. Grades of severity for anxiety and depression are examined against the patient profile in Tables 6 and 7 (Table 5).

Table 5: Psychiatric morbidity in the cohort (n = 100)

Status	n	%
Psychiatric morbidity present	53	53
No psychiatric morbidity	47	47
Total	100	100
Anxiety disorder (graded on HAM-A)	16	16
Depressive disorder (graded on HAM-D)	22	22

Of the 16 patients with anxiety, half (8) had mild, 5 moderate and 3 severe anxiety. Older patients predominated among mild cases, 37.5% being aged 51–60 years and a further 25% older than 60 years. Men outnumbered women in every grade (62.5%, 60.0% and 66.7% of mild, moderate and severe cases respectively), and married patients likewise formed roughly two-thirds of each grade. Patients who were illiterate or primary-educated together accounted for 75% of mild cases, and patients of lower socioeconomic status made up half of the mild cases. Despite these consistent gradients, none of the associations reached statistical significance (all $p > 0.05$) (Table 6).

Table 6: Distribution of patients with anxiety across sociodemographic categories (n = 16)

Variable	Category	Mild n (%)	Moderate n (%)	Severe n (%)	p-value
Age (years)	21–30	1 (12.5)	0 (0)	0 (0)	0.78
	31–40	1 (12.5)	2 (40)	0 (0)	
	41–50	1 (12.5)	1 (20)	1 (33.3)	
	51–60	3 (37.5)	1 (20)	1 (33.3)	
	>60	2 (25)	1 (20)	1 (33.3)	
Sex	Male	5 (62.5)	3 (60)	2 (66.7)	0.58
	Female	3 (37.5)	2 (40)	1 (33.3)	
Education	Illiterate	3 (37.5)	2 (40)	1 (33.3)	0.99
	Primary	3 (37.5)	1 (20)	1 (33.3)	
	Secondary/higher	2 (25.0)	1 (20)	1 (33.3)	
	Graduate	0 (0)	1 (20)	0 (0)	
Socioeconomic status	Lower	4 (50)	2 (40)	1 (33.3)	0.88
	Middle	3 (37.5)	1 (20)	1 (33.3)	
	Upper	1 (12.5)	2 (40)	1 (33.3)	
Marital status	Married	5 (62.5)	3 (60)	2 (66.7)	0.53
	Unmarried	3 (37.5)	2 (40)	1 (33.3)	
Total		8 (100)	5 (100)	3 (100)	

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Among the 22 patients with depression, 12 had mild, 5 moderate and 5 severe depression. Mild depression was most frequent in the oldest patients, one-third being older than 60 years and a quarter aged 51–60 years. Men constituted approximately 60% of cases in every grade. Illiterate patients formed the single largest educational category in mild, moderate and severe depression alike (41.7%, 40.0% and 40.0% respectively), and when combined with primary-educated patients accounted for 75% of mild and 80% of severe cases. Patients of lower socioeconomic status formed the largest group in each grade, and the proportion of married patients rose across grades from 58.3% in mild to 80.0% in severe depression. None of these associations was statistically significant (all $p > 0.05$) (Table 7).

Table 7: Distribution of patients with depression across sociodemographic categories (n = 22)

Variable	Category	Mild n (%)	Moderate n (%)	Severe n (%)	p-value
Age (years)	21–30	2 (16.7)	0 (0)	1 (20)	0.85
	31–40	1 (8.3)	2 (40)	1 (20)	
	41–50	2 (16.7)	1 (20)	1 (20)	
	51–60	3 (25)	1 (20)	1 (20)	
	>60	4 (33.3)	1 (20)	1 (20)	
Sex	Male	7 (58.3)	3 (60)	3 (60)	0.80
	Female	5 (41.7)	2 (40)	2 (40)	
Education	Illiterate	5 (41.7)	2 (40)	2 (40)	0.99
	Primary	4 (33.3)	1 (20)	2 (40)	
	Secondary/higher	3 (25)	1 (20)	1 (20)	
	Graduate	0 (0)	1 (20)	0 (0)	
Socioeconomic status	Lower	6 (50)	2 (40)	2 (40)	0.82
	Middle	4 (33.3)	1 (20)	2 (40)	
	Upper	2 (16.7)	2 (40)	1 (20)	
Marital status	Married	7 (58.3)	3 (60)	4 (80)	0.73
	Unmarried	5 (41.7)	2 (40)	1 (20)	
Total		12 (100)	5 (100)	5 (100)	

DISCUSSION

The profile that emerges is of a young to middle-aged, socioeconomically disadvantaged and physically multimorbid population. More than half the patients were aged 31–50 years, in keeping with the classical epidemiology of tuberculosis as a disease of the economically productive years, though our cohort was somewhat older than several Indian and Nepali series in which the modal age was 18–30 or 25–35 years [9,11,14]. A plausible explanation is delayed presentation in this rural population, where illiteracy, limited awareness of the disease, stigma about disclosure and poverty postpone health-seeking until symptoms are advanced. The near-equal sex distribution, with a slight female excess of 51%, contrasts with the male preponderance of 56% to 77% reported in most Indian series [9-11,15]; local reasons may include women concealing illness from their spouses, husbands who are sole earners being unwilling to accompany them for treatment, and initial recourse to traditional remedies in the villages.

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Low education and low socioeconomic position were prominent, with 43% illiterate or primary-educated and 84% belonging to the lower stratum, closely matching Tiwari *et al*., who reported that some 81% of their tuberculosis patients belonged to the lowest socioeconomic class [11], and consistent with the long-established association of tuberculosis with poverty, crowding and undernutrition [2,3]. The proportion married (82%) was likewise similar to the 71–82% reported elsewhere [10,11].

The physical comorbidity burden deserves particular emphasis. Hypertension affected 36%, chronic airway disease 39% when chronic obstructive pulmonary disease and asthma are combined, thyroid dysfunction 43%, and diabetes mellitus 19%. These figures are considerably higher than those in comparable series: Shyamala *et al*. reported hypertension in 16.8% and diabetes in 10.3% [9], while Jain *et al.* found 75% of their multidrug-resistant cohort free of comorbidity, with diabetes in 11% and hypertension in 8% [15]. The much higher rates here may reflect systematic ascertainment through clinical examination in a teaching hospital rather than reliance on patient report, an older cohort, and the recognized bidirectional relationship between tuberculosis and both diabetes [4] and chronic airway disease [5]. Whatever the explanation, a patient population in which chronic disease is this common cannot be managed adequately by a vertical TB programme alone, since polypharmacy, drug interactions, adverse effects and multiple clinic visits all threaten adherence [6].

Anxiety and depression were consistently concentrated among the illiterate, the poor, the married and men, and in the older age bands, yet no association attained statistical significance. This mirrors Salodia *et al*., who found no association of depression with sex, religion, marital status or education and concluded that male and female tuberculosis patients suffer alike [10], though it contrasts with Shrestha *et al*., who identified separated or widowed status and lower education as significant predictors of higher depression scores [14], and with Jain *et al*., who reported more severe depression in older patients [15]. Two explanations are likely here [15]. First, statistical power was limited, since only 16 and 22 patients had anxiety and depression respectively, leaving as few as three patients in some severity cells. Second, the cohort was highly homogeneous, with 84% in a single socioeconomic stratum and 82% married, so there was little variance against which to detect an effect. Further limitations include the single rural centre, the cross-sectional design, which cannot establish whether comorbidity preceded or followed psychological distress, and the absence of a recorded overall pulmonary to extrapulmonary ratio for the full cohort. Larger multicentre studies with urban comparison groups and longitudinal follow-up are needed; meanwhile, these findings support delivering tuberculosis care in rural India as an integrated chronic-care platform in which physical comorbidity, mental health and social vulnerability are addressed together [7,12,13].

CONCLUSIONS

Patients receiving DOTS-Plus therapy in this rural setting were predominantly in the economically productive years, almost equally divided between the sexes, poorly educated and overwhelmingly of lower socioeconomic status, and they carried a heavy burden of chronic physical illness— hypertension, thyroid dysfunction, chronic airway disease and diabetes mellitus. Anxiety and depression, present in 16% and 22% of the cohort respectively, clustered among the illiterate, the poor and the older patients, although the small numbers affected meant that no sociodemographic association reached statistical significance. Tuberculosis services in rural India should therefore be organized to screen for and manage physical comorbidity and psychological distress alongside antitubercular chemotherapy, with particular attention to illiterate and socioeconomically disadvantaged patients, and larger multicentre longitudinal studies are recommended to quantify these associations more precisely.

CONTRIBUTION OF AUTHORS

Research concept- Anusha VG, Anand M
Research design- Anusha VG, Vijayalaxmi Purad
Supervision- Kasturi Pandiyan
Materials- Vijayalaxmi Purad, Anand M
Data collection- Anusha VG, Vijayalaxmi Purad, Anand M
Data analysis and Interpretation- Kasturi Pandiyan
Literature search- Anusha VG, Vijayalaxmi Purad
Writing article- Anusha VG, Anand M
Critical review- Kasturi Pandiyan
Article editing- Anusha VG, Vijayalaxmi Purad, Anand M
Final approval- Kasturi Pandiyan

doi: 10.21276/SSR-IIJLS.2026.12.4.50

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